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Original Research

Local anaesthetic wound infiltration following paediatric appendicectomy: A randomised controlled trial
Time to stop using local anaesthetic wound infiltration following paediatric appendicectomy?

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ABSTRACT

Objective: This study sought to determine the efficacy of post-operative wound infiltration with local anaesthetic following paediatric appendicectomy.
Method: In a randomised, controlled, prospective, clinical trial children aged between five and sixteen years were assigned to one of three treatment arms; infiltration of the surgical wound with bupivicaine, saline, or no infiltration. Anaesthetic and analgesic protocols were employed. Patients and observers were blinded to the treatment group. The primary end-points were post-operative pain, scored at intervals during the first twenty post-operative hours, and additional post-operative analgesic requirements beyond that which was provided by a standard protocol. In addition, adverse wound outcomes were recorded.
Results: Eighty-eight children were recruited. There were no differences in age, sex or other confounding variables between groups. There was no significant difference in mean pain scores or analgesic requirements between groups through-out the post-operative period.
Conclusion: Wound infiltration with local anaesthetic following appendicectomy in children provides no additional benefit over regular simple analgesia. Its routine use represents dogmatic practise which ought to be challenged for this patient group.

1. Introduction

The infiltration of wounds with local anaesthetic as an adjunct to peri-operative pain control is widely practised. Proponents argue that we should only question 'why we are not using the technique?'[1] There is reasonable evidence for its efficacy in a range of procedures in the adult population,[2,3] although confounding results have also been published.[4,5] It would seem that whereas regional nerve blocks following abdominal wall incisions have fairly universal efficacy, wound infiltration alone may be of dubious benefit.

It has been previously reported that children require less post-operative analgesia than do adults following appendicectomy.[6] With questions regarding the benefit of the technique and the degree of analgesia required for this population, this study sought to determine the effect of post-operative wound infiltration with local anaesthetic following paediatric appendicectomy on post-operative pain.

2. Method

The trial was conducted in accordance with CONSORT guidelines. Following full ethical approval from the Plymouth Local Research Ethics Committee, consecutive paediatric patients from the age of five to sixteen years, under the care of a single consultant surgeon, undergoing appendicectomy through a right iliac fossa incision for clinically diagnosed appendicitis were considered for recruitment. Exclusion criteria are listed in Table 1.

The study was designed as a prospective randomised parallel clinical trial with three treatment arms; infiltration of the surgical wound with 0.5 ml kg^{-1} of 0.25% bupivicaine [LA], with 0.5 ml kg^{-1} of 0.9% saline [SAL], or no infiltration [NIL] (Fig. 1). Infiltration into the neurovascular plane and subcutaneous tissue took place prior to skin closure. Treatment allocation codes were generated using a computerised random number generator (Arcus Quickstat version 1.0) and were concealed in opaque envelopes to be revealed in theatre, immediately prior to wound closure. The patients and observers were blinded to the treatment group through-out the trial.

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Table 1
Exclusion criteria.

Exclusion criteria
ASA > II
Unable to take study medication
Withholding of parental consent
Appendicectomy not primary reason for surgery
Age <5 or >16

Participants followed a predetermined analgesic, anaesthetic and surgical protocol. An intravenous (i.v.) morphine bolus (0.1 mg kg^{-1}) was given at the time of diagnosis. Paracetamol (15 mg kg^{-1}) and diclofenac (1.5 mg kg^{-1}) were administered rectally at induction. All received a standard mode of anaesthesia (propofol, fentanyl (1 mcg kg^{-1}), suxamethonium, isoflurane). Additional peri-operative i.v. morphine was administered at the discretion of the anaesthetist using predefined physiological parameters as guidance. Post-operatively, regular oral paracetamol (15 mg kg^{-1}) six hourly and diclofenac (1.5 mg kg^{-1}) twelve hourly were prescribed. Break-through pain was treated with i.v. morphine in theatre recovery or oramorph (0.5 mg kg^{-1}) once on the ward. Thresholds for administration were prescriptive and based on objective pain scoring.

All appendicectomies performed by the investigating team were noted. Demographic details, concordance with trial protocol and permitted variables (including intra-operative opiate requirements, grade of surgeon operating and surgical approach) were recorded prospectively for each participant. The primary outcome measure was an objective pain score performed using Wong Bakers Faces (Fig. 2). This was conducted initially by recovery staff, and subsequently by ward nursing staff. Scoring began on arrival in recovery, occurring at 15 min intervals for the first hour, hourly for the first 4 h, and four hourly intervals until 20 h post-operatively. Levels of sedation were concurrently assessed using a five point scale as a surrogate marker for anaesthetic 'hang-over'. 'Break-through' analgesic requirements during the post-operative period and adverse wound outcomes constituted secondary outcome measures.

Data was recorded on source data sheets and transferred to a spreadsheet by the principal investigator. Analysis was performed using SPSS 11.5.1 (SPSS Inc 2001). Scale data were tested for normality and variance. Parametric data was analysed using a one way ANOVA and non-parametric data using a Kruskal-Wallis test. Comparisons of nominal data were made using the χ^2 test and pain and sedation scores using analysis of variance for repeated measures within groups. The sample size was estimated using SPSS Sample Power (SPSS Inc 2000), based on previously published estimates of pain score distribution, a 5% significance level, a clinical effect size of 35%, to give power of 80%.

3. Results

Over an 18 month period, 98 paediatric patients underwent open appendicectomy under the investigating team. 88 were eligible to complete the trial protocol. Reasons for exclusion included ASA > II, withholding of consent ($n = 2$) and protocol

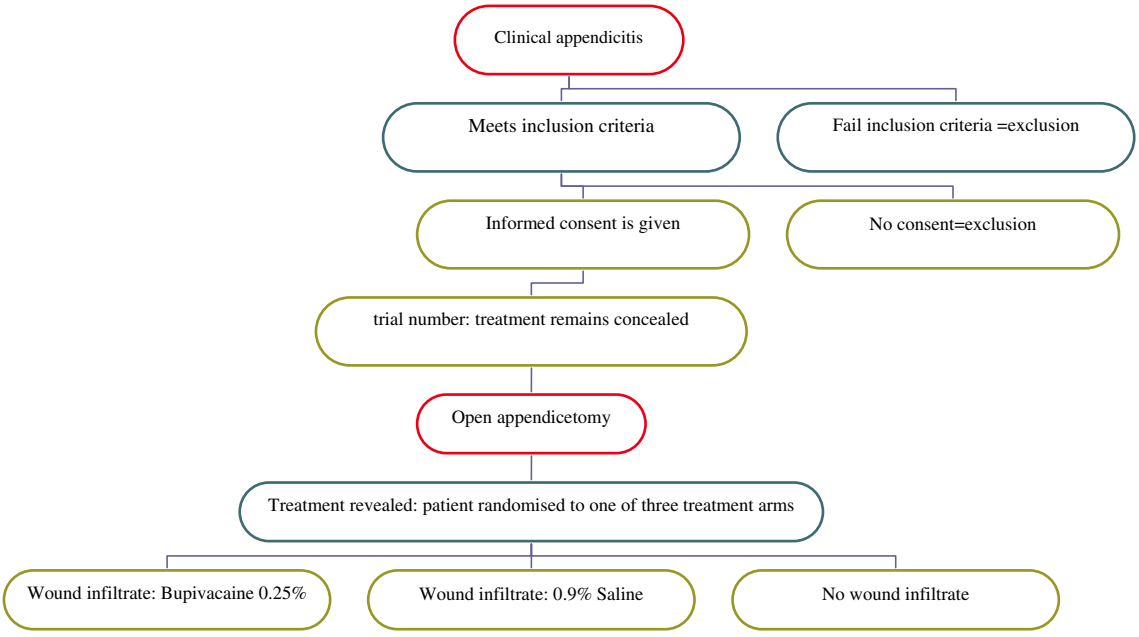


Fig. 1. Study protocol flow diagram.

Fig. 2. Wong Baker Faces used for objective pain scoring.

violations ($n = 7$). Participants were randomised to treatment groups; 29 to LA, 30 to SAL and 29 to NIL (Table 1).

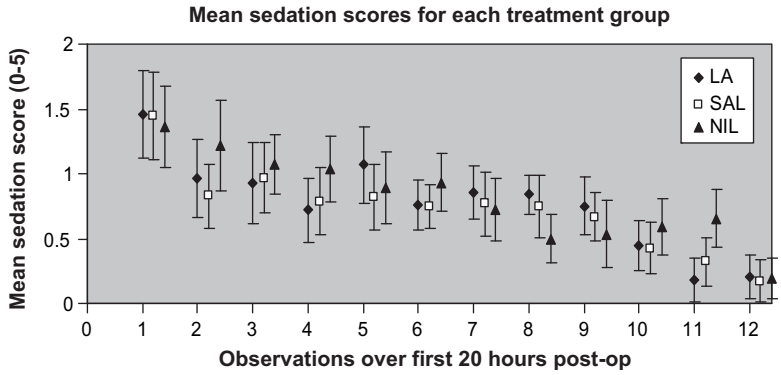
There was no significant difference in mean age, boy-girl ratios, intra-operative opiate requirements, grade of operating surgeon, or operative approach between groups (Table 2). Neither was there a significant difference in mean sedation scores between groups over the first hour ($p = 0.397$), 4 h ($p = 0.364$), or 20 h ($p = 0.972$) [Graph 1].

The mean pain scores for each group are displayed in Graph 2. ANOVA for repeated measures demonstrated a time effect on pain scores (decreasing pain) for all groups during the first hour and over 20 h ($p = 0.004$ and 0.023 respectively), but not over the first 4 h ($p = 0.326$). There was no evidence of a difference in mean pain scores between groups in any of the periods; the first hour ($p = 0.112$), first 4 h ($p = 0.097$), or first 20 h ($p = 0.209$). Neither was there evidence of any demonstrable interaction between treatment group and time over the first hour, 4 h and 20 h, $p = 0.891$, 0.631 and 0.081 respectively.

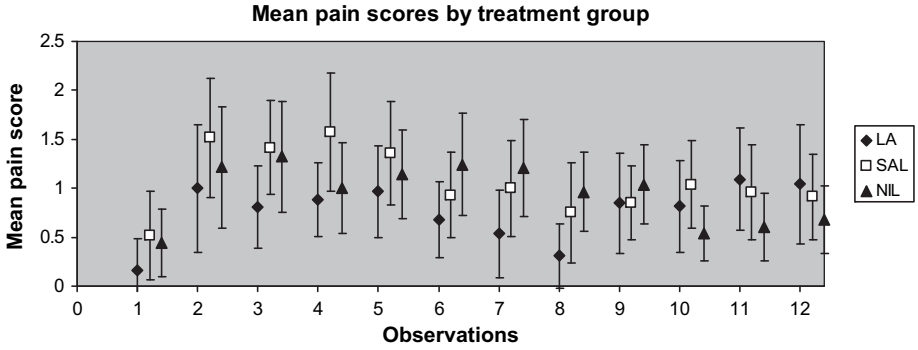
The median additional post-operative opiate requirement for all groups was 0 mg, with only 28%(LA), 30%(SAL) and 35%(NIL) requiring any break-through analgesia ($p = 0.846$ χ^2). The mean total dose required for each group was 4.66 mg (95%C.I. 1.06–8.25), 5.07 mg (95%C.I. 1.65–8.49) and 5.03 mg (95%C.I. 1.78–8.29) for LA, SAL and NIL respectively (Table 3).

Table 2
Comparison of potentially confounding variables between treatment groups.

Variable	LA	SAL	NIL	*p* value
Mean age(95% CI)	11.8 (10.8–12.9)	11.9 (10.8–13.1)	12.3 (11.3–13.3)	0.819 (ANOVA)
Boy: girl ratios	1.23: 1	1.14: 1	1.63: 1	0.708 (χ^2)
Median intra-op opiate requirement (range)	2.75 mg (0–12)	4 mg (0–10)	4 mg (0–10)	0.201 (Kruskal-Wallis)
Grade of surgeon; CONS: REG: SHO	13:12: 4	16: 10: 4	15: 9: 5	0.924 (χ^2)
Surgical approach; TR: muscle splitting	25: 4	27: 3	27: 2	0.686 (χ^2)



Graph 1. Mean sedation score in each treatment group at observation times 1–12. Y-error bars = two standard errors of the mean.



Graph 2. Mean pain score in each treatment group at observation times 1–12. Y-error bars = two standard errors of the mean.

Table 3
Comparison of secondary outcome measures between treatment groups.

Outcome measure	LA	SAL	NIL	*p* value
% Requiring additional opiates (95% CI)	28 (15–46)	30 (17–48)	35 (19–52)	0.846 (χ^2)
% Suffering adverse wound events (95% CI)	21 (10–38)	20 (10–37)	7 (2–22)	0.268 (χ^2)

There was no evidence for a difference in the number of adverse wound events between groups. Adverse events were recorded for 21% LA, 20% SAL and 7% NIL patients ranging from serous leak to superficial infection. The difference was not significant; $p = 0.268$ (χ^2) (Table 3).

4. Discussion

Having confidently excluded the presence of potentially confounding variables, it is clear that, whilst pain diminishes in all groups over the first 20 h, there is no significant difference in pain score, additional opiate requirements, or adverse wound events between treatment, placebo-control and control groups. These findings do not support previously published data.[7] The discrepancy may be explained by the provision of routine non-opioid oral analgesia in our study. Furthermore, the use of standardised anaesthetic, analgesic and surgical protocols, and utilising repeated assessment of pain scores through-out the post-operative period for each participant and the statistical comparison that form of data facilitates, increases the validity of these results.

Other corroborative evidence can be inferred from adult trials,[8] or paediatric trials for comparable (albeit inguinal) incisions.[9–12] In every case, wound infiltration is compared with an alternative locoregional technique rather than a control. As such, the efficacy of LA wound infiltration as an independent variable remains unproven.

A higher powered study may have allowed clinically significant differences of less than 35% to be detected. There are, however, no trends within the existing data to suggest that increasing the power would result in smaller differences being unearthed. The study was insufficiently powered to detect any difference in frequency of adverse wound events between groups. This was not the primary end-point.

Assessing pain is conceptually difficult. It is not readily quantifiable and has no fixed biological outcome measures. Use of objective pain assessment only may be criticised.[13,14] Commentators have suggested that inclusion of scoring by the child's parents[15] and subjective scoring by children as young as two[16] may be both valid and desirable when measuring pain in this population. Accepting these reservations, objective pain scoring was well conducted by observers already familiar with the method. In addition, the measures allowed appropriate comparative hypothesis testing to occur which encompassed the majority of the data.

5. Conclusion

In the context of regular non-opioid enteral analgesia, which conforms to the current surgical and anaesthetic guidelines for best practise,[17] the addition of post-operative local anaesthetic wound infiltration following paediatric appendicectomy has no discernable advantage, either in reducing objectively measured pain scores or requirements for additional opiate analgesia, when compared to either a placebo or control group. Regardless of whether one decides to abandon this practise, clinicians should be mindful of being distracted from basic priorities. The regular prescription and administration of simple analgesia through-out the peri-operative period for paediatric patients undergoing surgical interventions of this magnitude should be mandatory. Published audits of post-operative analgesic prescribing patterns within this population,[18,19] indicate that this is a message that needs to be restated.

Conflicts of interest
None declared.

Sources of funding
None declared.

Ethical approval
Yes Plymouth local research ethics committee Plymouth trial number 1145 25 February 1999.

ISRCTN

The trial was approved, initiated and completed recruitment prior to the mandatory/common use of clinical trials registries.

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